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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,165	07/26/2002	Paul B. Fisher	34585-A-PCT/USA070050.166	4970

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,165	FISHER ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-16-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 2-16-05 has been entered. Claims 1-8 and 10-19 have been canceled. Claim 9 has been amended. Claim 9 is pending and under consideration.

It should be noted that there are two versions of claims found in the instant application, one has claims 1-19 and one has claims 1-20 (amended sheet). Claim 20 was found on the claim pages, which are amended sheets, filed 9-21-01. Since applicants indicates that the instant application, filed as national stage filing of PCT/US00/06862 on march 15, 2000, contains only claims 1-19 not 1-20, therefore, only claims 1-19 are considered in the present application. In view of the amendment filed 2-16-05, claim 9 is pending and under consideration.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 9 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility and is repeated for the reasons set forth in the preceding Official action mailed 9-13-04. Applicant's arguments filed 2-16-05 have been fully considered but they are not persuasive.

Applicants argue that the utility of the instant invention is an improved and consistent expression of the reverse tetracycline controlled activator in tissues of a transgenic animal and there is no requirement to be associated with a disease or disorder. Applicants further argue that the vector of the present invention can be used to generate animal models and to identify useful pharmacological products and to monitor gene changes associated with aging, cancer and

development etc. (e.g. amendment, p. 6-7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 9-13-04. No phenotype of the claimed transgenic mouse has been disclosed and the claimed transgenic mouse is indistinguishable from wild type mouse. Since the claimed transgenic mouse has no phenotype, one of ordinary skill in the art would not know where to look at the effect of an agent and how to determine if a pharmacological product is useful in medical application by using said transgenic mouse. The specification fails to identify what disease or disorder is associated with the claimed transgenic mouse. There is no correlation between a phenotype of the claimed transgenic mouse and a particular disease or disorder. One of ordinary skill in the art would not know how to use the claimed transgenic mouse to identify an agent for treating a disease or a disorder, or to monitor gene changes associated with cellular process, such as aging, cancer and development etc. Basic research for studying the properties of a claimed product, a method of treating an unspecified disease or condition, and a method of assaying for or identifying a material that itself has "no specific and/or substantial utility" do not define "substantial utilities". Absent the phenotype of the claimed transgenic mouse and the correlation between a phenotype of said transgenic mouse and a particular disease or disorder, no "real world" use of the claimed transgenic mouse could be established. Therefore, the specification fails to provide an asserted specific and substantial utility or a well-established utility for the claimed transgenic mouse.

Applicants cite references A-G and argue that utility of tetracycline regulated transgenic animals is well-documented and the instant invention is an improvement of said transgenic animals (amendment, p. 7-8). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 9-13-04 and the following reasons:

(A) US patent 5,922,927 ('927) teaches a method for producing a transgenic mouse expressing a tetracycline-controllable transactivator (tTA), which is different from the reverse tetracycline controlled transactivator of the instant invention, and the promoter used in '927 is different from EF-1 alpha promoter of the instant invention. Further, no phenotype of the transgenic mouse in '927 has been disclosed, and even if there is a phenotype, the phenotype of the transgenic mouse of '927 would be different from that of the claimed transgenic mouse of the instant invention because different transgene and promoter are used and the resulting phenotypes of a transgenic animal depend on individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, and the site of integration.

(B) US Patent 5,917,122 ('122) teaches a transgenic mouse comprising an optimized tetR gene under the control of PEPCK promoter, which are different from the reverse tetracycline controlled transactivator and the EF-1 alpha promoter of the instant invention. The phenotype of the transgenic mouse of '122 would be different from that of the claimed transgenic mouse of the instant invention because different transgene and promoter are used and the resulting phenotypes of a transgenic animal depend on individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, and the site of integration.

(C) US Patent 5,912,411 ('411) teaches a transgenic mouse comprising not only a transgene encoding mutated Tet repressor but also a gene that confers a detectable and functional phenotype on the mouse. The transgenes and promoter used in the transgenic mouse of '411 are different from that of the claimed transgenic mouse of instant invention. As discussed above, the phenotype of the transgenic mouse of '411 would be different from that of the claimed transgenic mouse of the instant invention because different transgene and promoter are used and

the resulting phenotypes of a transgenic animal depend on individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, and the site of integration.

(D) Chin et al., 1999, discloses a trasngenic mouse line harbouring the reverse tetracycline transactivator (rtTA) under the control of tyrosinase gene promoter-enhancer elements, and the use of said transgenic mouse to corss with a transgenic mouse containing H-Ras ^{V12G} open reading frame driven by minimal promoter to generate single and double transgenic mice that are homozygous null for INK4a. The promoter used for the transgenic mouse harboring rtTA is different from that of the claimed transgenic mouse of the instant invention and no phenotype has been disclosed for said transgenic mouse of Chin. Further, the transgenic mouse harboring rtTA of Chin was used to cross with another transgenic mouse to generate totally different transgenic mice having dramatically different phenotypes and uses. Thus, the phenotype of the transgenic mouse, before or after crossing with other transgenic mouse line, of Chin would be different from that of the claimed transgenic mouse of the instant invention. The claimed transgenic mouse of instant invention still lacks an asserted specific and substantial utility or a well-established utility.

(E) Chin et al., 2000, teaches double transgenic mice harboring tyrosinase-driven rtTA and tetO-RAS (e.g. p. 148, right column). As discussed in (D), the promoter used for the transgenic mouse harboring rtTA is different from that of the claimed transgenic mouse and no phenotype of the claimed transgenic mouse of the instant invention has been disclosed. The phenotype of the double transgenic mouse of Chin would be different from that of the claimed transgenic mouse of the instant invention, if there is any. Thus, the claimed transgenic mouse of

instant invention still lacks an asserted specific and substantial utility or a well-established utility.

(F) Wang et al., 2004, does not teach generation of a transgenic mouse harboring rtTA under the control of a promoter.

(G) Vitale-Cross et al., 2004, teaches generation of a transgenic mouse carrying tet-on receptor and said transgenic mouse was crossed with mice expressing the K-ras ^{G12D} oncogene under the control of tet-regulated responsive elements (e.g. abstract). The claimed transgenic mouse of instant invention still lacks an asserted specific and substantial utility or a well-established utility for the same reasons as set forth in (D) and (E).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 9 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 9-13-04. Applicant's arguments filed 2-16-05 have been fully considered but they are not persuasive.

Applicants amended claim 9 to be limited to mice and argue that the claim is enabled (amendment, p. 10). This is not found persuasive because of the reasons set forth in the

preceding Official action mailed 9-13-04 and the reasons set forth above under 35 U.S.C. 101 utility rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Shin-Lin Chen, Ph.D.